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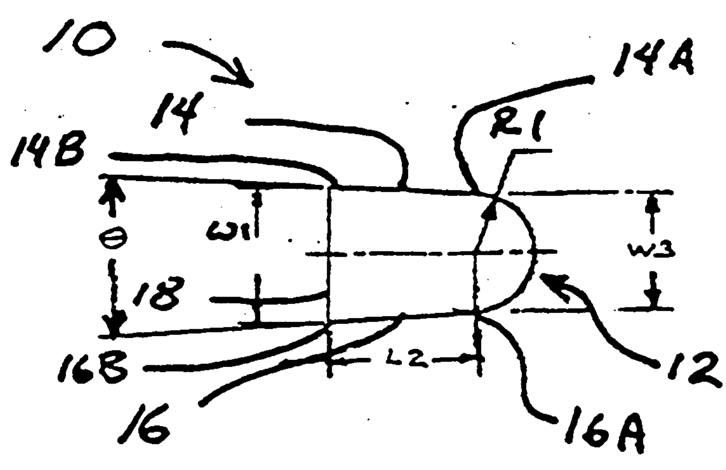
(57) Abstract

An intervertebral spacer or implant (10) is disclosed which has a rapidly tapering presenting portion (12) and two opposed lateral surfaces (14 and 16). The presenting portion (12) can include a semicircular region having a radius (R1) when viewed from an elevation orientation, and comprises a second semicircular region having a radius (R2) when viewed from a plan orientation. The opposed lateral surfaces (14 and 16) each include posterior end (14A and 16A), respectively, and anterior end (14B and 16B), respectively. The opposed lateral surfaces (14 and 16) taper away from each other at an angle theta, preferably in the range of 5 degrees to 8 degrees.



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INTERVERTEBRAL SPACER

BACKGROUND OF INVENTION

1. FIELD OF THE INVENTION

The present invention pertains to an intervertebral spacer for promoting anterior intervertebral fusion in a patient.

2. BRIEF DESCRIPTION OF THE PRIOR ART

The presacral vertebrae of the human spine are normally held in a precise relation to each other by intervertebral disks, longitudinal ligaments, and the musculature of the body.

These vertebrae can move relative to adjacent vertebrae in various manners, permitting the head to be turned relative to the body and providing a wide range of flexibility to the spine. The movement between individual pairs of vertebrae is limited, however, to prevent local pressure on, or excessive bending of, the spinal cord. Such pressure or bending could result in disorders associated with blockage of the nerve impulses traveling along the spinal cord, in turn producing pain, paresthesia, or loss of motor control, which must be resolved by removing the causative condition.

Nerve conduction disorders may also be associated with the intervertebral disks or the bones themselves. One such condition is a herniation of the intervertebral disk, in which a small amount of tissue protrudes from the sides of the disk into the foramen to compress the spinal cord or nerve roots. A second common condition involves the development of small bone spurs, termed osteophytes, along the posterior surface of the vertebral body, again impinging on the spinal cord or nerve roots.

Upon identification of the abnormality causing the conduction disorders, surgery may be required to correct

the problem if more conservative treatment fails. For those problems associated with the formation of osteophytes or herniations of the intervertebral disk, one such surgical procedure is intervertebral discectomy. In this procedure, the involved vertebral bodies are exposed and the intervertebral disk is removed, thus removing the offending tissue, or providing access for the removal of the bone osteophytes. A second procedure, termed a spinal fusion, may then be required to fix the vertebral bodies together to prevent movement and maintain the space originally occupied by the intervertebral disk. Although some minor loss of flexibility in the spine may result, because of the large number of vertebrae and other motions in the hip and shoulder joints the loss of mobility is usually acceptable.

During a spinal fusion following a discectomy, an implant may be inserted into the intervertebral space. This intervertebral implant is often autologous bone, i.e., a bone graft removed from another portion of the patient's body, termed an "autograft." The use of bone taken from the patient's body has the important advantage of avoiding rejection of the implant, but has some shortcomings. There is always a risk in opening a second surgical site for obtaining the implant, which can lead to infection, pain, or donor site morbidity for the patient, and the site of the implant is weakened by the removal of bony material. The bone implant may not be perfectly shaped and placed, leading to slippage or absorption of the implant, or failure of the implant to fuse with the vertebrae.

Other options for a graft source for the implant are bone removed from cadavers, termed an "allograft," or from another species, termed a "xenograft." In these cases, while there is the benefit of not having a second surgical

site as a possible source of infection, pain, or donor site morbidity, there is, in addition to the other problems associated with an autograft, the increased difficulty with graft rejection and the risk of transmitting communicable diseases. Additionally, allograft bone loses up to half its strength during the first six months and may remain weakened for another six months following surgery, which exceeds any realistic period of immobilization or clinical protection of the neck for this potential mechanical weakening interval of 12 months. Fibular allograft usually has no central structural content, and as well as subsidence, may have delayed healing. Both allograft and autograft may have late resorption with successful union, leaving the long-term reconstruction of sagittal alignment unreliable.

An alternative approach to using a bone graft is to use a manufactured implant made of a synthetic material that is biologically compatible with the body and the vertebrae. Several compositions and geometries of such implants have been utilized, ranging from simple blocks of material to carefully shaped implants, with varying success. No fully satisfactory implant has yet been reported, however. In some instances, the implanting surgery is readily accomplished, but the results are unsatisfactory due to side effects or dislocation of the implant. In other instances, the implant requires a complex surgical procedure that is difficult to perform and still may not lead to correction of the problem for the reasons indicated.

One attempt at solving the aforementioned shortcomings of the prior art is disclosed in PCT application PCT/US92/05859. In this application, an implant comprising a generally rectangular block of hydroxylapatite is

disclosed, the block having a pattern of serrations to prevent slippage following implantation, and a ridge on at least one transverse face of the implant to assist in positioning and maintaining the implant between adjacent vertebrae. In this device, the use of the ridge requires using a drill to create a groove in either or both of the superior and inferior vertebrae, in order to shape the vertebrae to complement the shape of the ridge(s). This requirement of fashioning grooves in the vertebrae obviously increases the risk of complications during and after the implant procedure, including weakening of the adjacent vertebrae, risking fracture or subsidence with time and healing, which results also in loss of maintenance of the corrected sagittal alignment. Further, the vertebrae and plates are a complex shape, with the intervertebral joints often likened to "saddle joints", which do not suit a rectangular graft end with a groove for the ridge. Failure to consider the complex anatomy of the intervertebral space and reluctance to destroy the strong cortical vertebral endplate to shape it to suit an artificial implant leads to less than optional contact areas to unite, stress concentrations, and dislodgement.

There is therefore a need for an improved spinal disk implant, which is both readily utilized in a surgical procedure and has a high probability of success without undesirable side effects. The present invention fulfills this need, and further provides related advantages.

SUMMARY OF INVENTION

The present invention provides a surgical implant, and its method of use, wherein the implant is implanted between two vertebrae during a procedure following which the two vertebrae are fused together. The surgical disk implant is readily manufactured of biologically compatible materials

in the required shape and with preselected dimensions, so that a properly dimensioned implant is available for the particular vertebrae being fused together. The disk implant of the invention may be readily implanted by established surgical procedures, with minimal changes of surgical difficulty. The geometry of the implant ensures good load bearing and support through the fused vertebrae, and minimizes the likelihood of the implant dislocating relative to the vertebrae either during surgery or during the post-operative fusing process.

In accordance with a highly preferred embodiment of the invention, an intervertebral spacer for promoting anterior intervertebral fusion in a patient comprises a solid body having a rapidly tapering presenting portion comprising the posterior end of the spacer, the spacer further including a pair of spaced-apart, opposed lateral surfaces, each lateral surface having an anterior end and a posterior end, the lateral surfaces being joined at their posterior ends by the rapidly tapering presenting portion. The lateral surfaces taper apart from one another from their posterior ends to their anterior ends, and are joined at their anterior ends by a face comprising a trailing edge portion.

As will subsequently be described, the unique shape of the implant of the invention allows it to be used virtually universally in patients without requirement for serrations or shaping grooves in the vertebrae. Unlike previous art, this unique shape restores and maintains normal sagittal alignment of the spine.

BRIEF DESCRIPTION OF THE DRAWINGS

The foregoing and other objects, aspects, and advantages will be better understood and more readily apparent to those of ordinary skill in the art as the

following detailed description of the preferred embodiments of the invention proceeds, particularly with reference to the accompanying illustrative Figures, in which:

Figure 1A is a lateral elevational view of a preferred spacer of the present invention.

Figure 1B is a top plan view of the spacer illustrated in Figure 1A.

Figure 1C is a left side elevational view of the spacer of Figure 1A.

Figure 2 is a preoperative lateral x-ray of a patient, with C5-6 kyphosis of 3°.

Figure 3 is a postoperative lateral x-ray of the same patient of Figure 2, following surgical implant, with a hydroxyapatite spacer of the present invention distracting the interspace and producing 7° of cervical lordosis at C5-6.

Figure 4A is a lateral elevational view of a preferred spacer of the present invention.

Figure 4B is a top plan view of the spacer illustrated in Figure 4A.

Figure 4C is a left side elevational view of the spacer of Figure 4A.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to Figure 1A, a preferred implant or spacer of the present invention, generally 10, is illustrated. As shown, the implant includes a rapidly tapering presenting portion, generally 12, which tapers rapidly from two opposed lateral surfaces 14 and 16. In the embodiment of Figure 1A, the presenting portion 12 comprises a semi-circular region having a radius R1 when viewed from an elevational orientation, and comprises a second semi-circular region having a radius R2 when viewed from a plan orientation as illustrated in Figure 1B. In a highly

preferred embodiment of the invention, the radius R1 is .138 inches (3.46 mm) and the radius R2 is ..236 inches (5.78 mm). Of course, other combinations of radius dimension and other tapering shapes, including by way of example but not limitation, ellipsoidal and conical tapering sections for the presenting portion 12 would be possible, as will now be appreciated by those of ordinary skill in the art. All such shapes are specifically embraced within the meaning of "rapidly tapering" as used herein.

In the embodiment of Figures 1A and 1B, the rapidly tapering presenting portion 12 tapers to a convex tip, which enables the spacer 10 to function in wedge-like fashion, facilitating insertion and implantation of the spacer in a patient.

As illustrated in Figure 1A, the opposed lateral surfaces 14 and 16 each include a posterior end 14A and 16A, and an anterior end 14B and 16B, respectively. The lateral surfaces 14 and 16 are joined at their posterior ends 14A and 16A by the rapidly tapering presenting portion 12. Most preferably, the lateral surfaces 14 and 16 taper apart from one another from their posterior ends 14A, 16A to their anterior ends 14B, 16B, by an angle O, as illustrated in Figure 1A. Although this taper may vary, a taper of 5-8 degrees has proven preferable, with a most preferred embodiment having a taper of 6 degrees 46'. The taper angle approximates the degree of cervical lordosis produced between adjacent vertebrae when the implant 10 is implanted. The anterior and posterior ends 14B, 16B of the opposed lateral surfaces 14, 16 are preferably joined by a face portion 18 comprising a trailing edge of the implant. It is this face 18 that the surgeon impacts in order to insert the implant into a patient as will subsequently be

described.

Referring now to Figure 1C, when the implant of the present invention is viewed perpendicularly to the face 18 comprising the trailing edge portion, it is evident that at least one, and preferably both, of the opposed lateral surfaces 14, 16 include a convex portion. Most preferably, this convex portion extends the entire length L2 of the opposed lateral surfaces. In a highly preferred embodiment of the invention, the convex portions of the opposed lateral surfaces 14, 16 join at the face 18 to create an ellipsoidal shape, as illustrated in Figure 1C. Of course, as will now be readily appreciated to those of ordinary skill in the art, other shapes, such as oval and other curvilinear segments, such as round, hyperbolic, parabolic, etc., could be employed for the convex portion of the opposed lateral surfaces 14 and/or 16 and/or the curvilinear surfaces shown as radiused R1 and R2. While it is preferred that both opposed lateral surfaces 14, 16 include a convex portion, it would be possible to employ only one convex portion on one opposed lateral surface. As illustrated in Figures 1B and 1C, the opposed lateral surfaces 14 and 16 preferably meet at parallel surfaces 20, 22.

In a highly preferred embodiment of the invention, the spacer implant is universal in size for cervical application for adult human patients, being about 11-13 millimeters in length (L1), the presenting portion 12 being about 3-5 millimeters in length (L3) and about 4-6 millimeters in width (W3) when viewed perpendicularly from an elevational view (Figure 1A), the presenting portion 12 further being about 6-8 millimeters in width (W2) when viewed perpendicularly from a plan view (Figure 1B). The presenting portion preferably meets the opposed lateral

surfaces approximately 4-5 millimeters (L3) from the posterior end of the implant. Additionally, the trailing edge portion 18 is preferably about 6-8 millimeters at its widest point (W1) when viewed perpendicularly in an elevational view (Figure 1C) of the spacer. The trailing edge portion 18 is also preferably about 11-13 millimeters in width (W2) when the spacer is viewed perpendicularly from an elevational view (Figure 1C).

A most highly preferred embodiment of the invention is illustrated in Figures 4A-C. In this embodiment, the width W2 has been stretched out by a distance W4 relative to the spacer illustrated in Figure 1C. This region W4 is preferably flat, and increases the contact between the implant and the spinal end plates. The embodiment illustrated in Figure 4C continues to include the elliptical ends, joined in the middle by the flat region W4 as illustrated, however, as previously discussed, other curvilinear segments could also be used.

As illustrated in the top plan view of Figure 4B, the width W4 comprises a flat portion on the presenting portion 12 of the implant. This flat portion W4 is joined to the parallel surfaces 20 and 22 by radiused sections 30 each having a radius R2. Alternatively, the radiused sections 30 may comprise segments of other curvilinear shapes.

As illustrated in Figure 4A, the lateral elevational view of the spacer remains unchanged from that of Figures 1A-1C.

In a most highly preferred embodiment of the invention of Figures 4A-C, W1=7 millimeters, W2=15 millimeters, W3=4 millimeters, W4=3 millimeters, L1=12 millimeters, L2=8 millimeters, and L3=4 millimeters. Other dimensions are, of course, possible. Other areas of the spinal column, such as the lumbar region, would require proportionate

sizing for W1, W2, W3, W4, L1, L2, and L3, which will now be readily apparent to one of ordinary skill in the art.

The implant 10 is desirably made from a material that, after surgical implantation, bonds to the natural bone of the adjacent vertebrae to form a rigid structure. The implant is preferably made from a ceramic, most preferably a hydroxyapatite such as calcium hydroxylapatite, having a chemical formula $Ca_{10}(PO_4)_6(OH)_2$, available from Smith & Nephew Richards, Inc., 1450 Brooks Road, Memphis, Tennessee 38116 U.S.A. The use of such materials in implants is known, see for example U.S. Patent No. 4,863,476, whose disclosure is incorporated in its entirety by reference herein. The implant 10 may also be made from a composite material, such as the carbon-fiber reinforced material disclosed in U.S. Patent No. 4,904,261, also incorporated in its entirety by reference herein. The implant 10 may also be made from a biocompatible orthopedic polymer ("BOP"), such as a copolymer of methylmethacrylate and N-vinylpyrrolidone and calcium gluconate, reinforced with polyamide fibers. Such a material is known in the art, and is described, for example, in G. Lozes et al., "Discectomies of the Lower Cervical spine Using Interbody Biopolymer (BOP) Implants," Acta Neurochir (Wien), vol. 96, pages 88-93 (1989). In some instances, the implant may be made from an uncoated biocompatible metal, such a titanium or a titanium alloy such as Ti-6Al-4V, or a nonreactive metal such as gold, or such a metal coated with a layer of the ceramic.

In another approach for the construction of the implant, a coated implant is prepared by providing a piece of metal, preferably a non-reactive biocompatible metal, such as titanium, titanium alloy, stainless steel, gold, vanadium/aluminum alloys, or other metals and alloys known

in the art, in the shape of the implant but slightly undersized in all dimensions. A coating of ceramic or polymer, of the types described previously, is applied over the piece of metal to enlarge the implant to the proper final dimensions. Such construction is described in PCT Application PCT/US92/05859, incorporated in its entirety by reference herein.

The implant 10 may be solid or hollow, and may be made microporous, so that it functions as a delivery vehicle for antibiotics or bone stimulating factors such as bone morphogenic protein or osteogenin, which are introduced into the implant before implantation surgery. In the case of the preferred ceramic hydroxylapatite construction of the implant, the density and/or surface morphology of the ceramic can be varied in the sintering process so that it retains the materials to be delivered. The delivery of chemicals by this approach is known in the art, see, for example, H.A. Benghuzzi et al., "The Effects of Density of the Ceramic Delivery Devices on Sustained Release of Androgens in Castrated Rodents," 17th Annual Meeting of the Society of Biomaterials, May 1-5, 1991, page 159.

The spacer of the present invention is shaped using any acceptable method, and in the case of solid hydroxylapatite as the material, the brittleness of this material suggests the use of high speed diamond tools as a preferred approach to contour and shape the implant.

Because of the unique shape of the implant 10, including the rapidly tapering presenting portion 12, and the outwardly tapering opposed lateral convex surfaces 14, 16 the implant 10 seats itself quite readily between adjacent vertebrae, as seen in Figure 3, eliminating the need for serrations, ridges requiring grooving of vertebrae, and excessive impaction force for implantation.

In addition to the cervical lordosis achieved according to a preferred embodiment of the invention, it is also within the scope of the present invention to advantageously restore lumbar lordosis to the spine. In a highly preferred embodiment of the invention, an implant having the unique shape described herein is implanted in the lumbar region of the spine, restoring normal sagittal alignment of the spine.

The effectiveness of the implant of the present invention is further demonstrated by the following examples.

Surgical Technique

After the induction of an adequate general endotracheal anesthesia, including placement of an esophageal tube for anesthesia monitoring, and intraoperative identification for protection of the esophagus, the patient was positioned on the operating table. A halter was placed on the anterior part of the neck and taped to the chin, so that it would not slide down during surgical prep or up during application of traction, and was attached to a traction spreader bar for intraoperative axial distraction. A triangular roll was placed under the scapulae to elevate shoulders and trunk, and muslin tied to the operating table over ABD pads on the shoulders to maintain the position of the patient during traction for intraoperative x-ray when the lower cervical disc spaces were involved. Towels and a donut were placed under the head, which were removed to provide mild extension of the neck to facilitate graft insertion (Figure 2). Somatosensory evoked potentials were used and applied prior to patient positioning when a myelopathy was suspected or present, as opposed to a pure radiculopathy without spinal stenosis.

Skin creases were marked after the neck was prepped

with Betadine and alcohol over the incisional area, with the head turned about 45° to the right to retract the visceral structures. A left approach is preferred because of the constancy of the recurrent laryngeal nerve on that side. After incising the skin, the platysma was divided horizontally in the line of the incision, and then a vertical fascial incision was made medial to the sternocleidomastoid, and deepened with finger dissection to the anterior cervical spine, leaving the carotid sheath lateral and the midline structures retracted by head positioning. Cervical retractors were used on each side out to the longus colli, thus exposing the anterior cervical spine. After palpation of the disc spaces, a doubly bent 18 gauge needle (to prevent excess needle penetration) was inserted into the disc space and an x-ray taken to confirm level of the needle. Generally an anterior spur or some other identifying mark, such as the carotid tubercle, is used to identify the level and direct needle insertion.

Using this exposure, the anterior longitudinal ligament was excised with a 15 blade, and the disc was then removed with a pituitary rongeur under microscope visualization. A freer was used to develop a plane between the bony endplate of the vertebral body and the cartilaginous endplate, to facilitate dissection down to the posterior lip of the vertebral body. The posterior longitudinal ligament was visualized and retained, except when disc material was suspected to have herniated through the ligament, or if prominent uncovertebral spurs were present causing foraminal encroachment and were elected to be curetted or removed. After thorough removal of disc material, a Hall burr was used to prepare the endplates without significant disruption, but allowing bleeding for

incorporation of the bone graft or hydroxyapatite.

The spacer was cut from a block of the hydroxyapatite material with a Midas Rex diamond wheel (WH-1) and then shaped as set forth in Figures 1A, 1B, and 1C to approximate the concave vertebral endplates of the saddle joint of the cervical spine. Careful contouring of the material was performed to reduce stress concentration and eliminate subsequent subsidence of the implant with the leading edge reduced to about 4 mm for easy insertion into the disc space. The block was then contoured to a maximum of 7 mm in height, with the leading edge tapered to about 6 mm following a small radius of curvature from the presenting leading edge, attempting to match the posterior lip of the endplate of the superior vertebral body and thus nestle into this space (Figure 3). After shaping with the Midas Rex, the implant was impacted with care to follow the direction of the disc space, particularly the lower cervical levels which are directed somewhat cephalad, while the neck was in mild extension by removing the cervical donut and having the anesthesiologist apply halter traction to open the intervertebral disc space. X-ray confirmation of position was performed to not only evaluate depth of penetration but also evaluate sagittal alignment and distraction of the intervertebral disc space, as seen in Figure 3, which shows a post operative lateral x-ray of a hydroxylapatite spacer of the present invention distracting the interspace and producing 7° of cervical lordosis at C4-5.

The wound was subsequently lavaged and closed with dissolvable sutures in the platysma, subcutaneous tissues, and then a subcuticular skin closure with Steri-strips was used. The anterior lip of the cephalad vertebral body was retained when possible, as the customary osteophyte at this

point was felt to potentially resist dislodgement of the graft and did not obstruct graft insertion. Gauze bandages were placed over the subcuticular closure usually without tape, and the patient was placed in a Philadelphia collar to then be reversed, extubated, and taken to the recovery room.

The Philadelphia collar was used for a period of six weeks with follow-up x-rays shortly after surgery and at six weeks. Following adequate reduction of prevertebral fascia swelling and resolution of the patient's symptoms, the patient was weaned from the collar over the next several days to two weeks with subsequent resumption of range-of-motion exercises, and when appropriate, isometric exercises or formal physical therapy, if needed. Generally, full activities were resumed at two months. Trabeculae could generally be seen crossing from the adjacent vertebral bodies into the graft with autologous bone, so the time course was more clinically determined but supplemented by current practice with other uses of hydroxyapatite, such as coated prostheses.

Case Study #1. K.L. is a 43-year-old white female, who had presented with a myelopathy, including hyperactive lower extremity reflexes and bilateral Babinskis, but with minimal radiculopathy and failed conservative therapy. A large central disc herniation was noted on MRI (Figure 2) and she elected to proceed with surgical intervention.

The procedure was performed as described with somatosensory evoked potentials monitored and which returned to normal during the operative procedure. Preoperative and postoperative x-rays are illustrated in Figures 2 and 3, respectively, with correction of sagittal alignment and adequate intervertebral disc height restoration.

This patient returned to work as a school teacher at two weeks' time, and was weaned from the collar at the six week point. In the next two weeks, she essentially was returned to full normal activities with resolution of lower extremity numbness, normal gait, and was discharged at two months' time. The patient was called back and obtained a follow-up long-term x-ray at six months (Figure 3).

Discussion

The use of hydroxyapatite spacer of the present invention provides a reliable sagittal alignment, which has been increasingly recognized significant in the lumbar spine, and with maintenance of intervertebral disc height, which indirectly decompressing the neural foremen. The ability to predictably reconstruct sagittal alignment and maintain foraminal decompression is particularly important with multilevel fusions, or revisions done sequentially over several years in patients with chronic pain. Such cases may have diminished vascularity, scar from previous procedures, and residual sagittal plane deformity. While the stress at adjacent levels is presumably from immobilization due to the fusion, disruption of the contiguous sagittal alignment may contribute to increased stress with subsequent degeneration in adjacent levels and potentially pain. The expectation for osteophytes over the ensuing several years is that they will resorb, but a radiculopathy deserves prompt relief for which the use of the microscope allows resection.

The dense, solid hydroxyapatite material is selected for maximal strength. Porous material may be adequate for the cervical spine, but like bone graft, is not anticipated to be as reliable for maintaining sagittal alignment and foraminal decompression. The brittleness of hydroxyapatite has suggested the use of high speed diamond tools to

contour and shape the material, and special care on insertion. The described technique allows rapid incorporation and return to full function on the time schedule of autologous bone, but without the donor site morbidity. This bone substitute avoids the risks of bank bone, such as delayed incorporation, and subsidence with late loss of sagittal correction or disc height distraction through immunologic reaction, delaying healing, or potentially, fatigue fracture.

The invention in its broader aspects is not limited to the specific details of the preferred embodiments shown and described, and those of ordinary skill in the art will recognize that the invention can be practiced with modifications within the spirit and scope of the appended claims, including any and all equivalents thereof. Additionally, although certain preferred embodiments of the invention described herein satisfy one or more objects and provide one or more advantages as discussed above, it is expressly contemplated that the invention may be practiced in spirit without utilizing all of the objects and advantages, and that accordingly, the objects and advantages of the invention form no part thereof, except as such may be embodied by the full scope of the following claims.

I Claim:

1. An intervertebral spacer means for promoting anterior intervertebral fusion and sagittal alignment in a patient, said spacer means comprising a body having a rapidly tapering presenting portion comprising the posterior end of said spacer means, said spacer means further including a pair of spaced-apart, opposed lateral surfaces, each lateral surface having an anterior end and a posterior end, said lateral surfaces being joined at their posterior ends by said rapidly tapering presenting portion, said lateral surfaces tapering apart from one another from their posterior ends to their anterior ends and being joined at their anterior ends by a face comprising a trailing edge portion.

2. The spacer means of Claim 1, wherein at least one of said opposed lateral surfaces includes a convex portion, as viewed perpendicularly to the face comprising the trailing edge portion.

3. The spacer means of Claim 1, wherein said rapidly tapering presenting portion tapers to a convex tip, when viewed from both elevational and plan views of said spacer means.

4. The spacer means of Claim 3, wherein said spacer means is curvilinear in shape, when viewed perpendicularly from both the anterior and posterior ends thereof.

5. The spacer means of Claim 4, wherein said spacer means includes a pair of parallel side portions when viewed from a plan view thereof.

6. The spacer means of Claim 1, wherein the spacer means comprises a material that bonds to natural bone.

7. The spacer means of Claim 1, wherein the spacer means comprises, at least in part, natural bone, a

biocompatible orthopedic polymer material, a ceramic, a ceramic-coated metal, a composite, or a metal.

8. The spacer means of Claim 7, wherein the ceramic is hydroxyapatite.

9. The spacer means of Claim 7, wherein the metal is selected from the group consisting of titanium, titanium alloys, gold, vanadium/aluminum alloys, and stainless steel.

10. The spacer means of Claim 1, wherein the implant is microporous.

11. The spacer means of Claim 1, wherein the spacer means is universal in size for promoting anterior cervical fusion in adult human patients, being about 11-16 mm in length, the presenting portion being about 3-5 mm in length and being about 4-6 mm in width when said spacer means is viewed perpendicularly from an elevational view, the presenting portion further being about 6-8 mm in width when said spacer means is viewed perpendicularly from a plan view, the trailing edge portion being about 6-8 mm at its widest point when said spacer means is viewed perpendicularly from an elevational view and about 11-16 mm at its widest point when said spacer means is viewed perpendicularly from a plan view thereof.

12. The spacer means of Claim 11, wherein the spacer means being about 12 mm in length, the presenting portion being about 4 mm in length and being about 4-6 mm in height when said spacer means is viewed perpendicularly from an elevational view, the presenting portion further being about 7 mm in width at its widest point when said spacer means is viewed perpendicularly from a plan view, the trailing edge portion being about 7 mm in height at its widest point when said spacer means is viewed perpendicularly from the anterior end and about 15 mm in width at its widest point when said spacer means is viewed perpendicularly from the anterior end thereof.

13. The spacer means of Claim 12 wherein said face of said trailing edge includes ellipsoidal sections, and both

opposed lateral surfaces have a convex contour corresponding to said ellipsoidal sections of said trailing edge.

14. A system for promoting sagittal alignment of a patient's spine, comprising an intervertebral spacer means for promoting anterior intervertebral fusion in said patient, said spacer means comprising a solid body having a rapidly tapering presenting portion comprising the posterior end of said spacer means, said spacer means further including a pair of spaced-apart, opposed lateral surfaces, each lateral surface having an anterior end and a posterior end, said lateral surfaces being joined at their posterior ends by said rapidly tapering presenting portion, said lateral surfaces tapering apart from one another from their posterior ends to their anterior ends and being joined at their anterior ends by a face comprising a trailing edge portion, said system providing anterior and posterior sagittal alignment in a region of said spine in which said spacer means is implanted.

15. An intervertebral spacer means for promoting anterior intervertebral fusion and sagittal alignment in a patient, said spacer means having a rapidly tapering presenting portion, said presenting portion having curvilinear segments in any plane of view of said presenting portion, said presenting portion tapering to an apex comprising the posterior end of said spacer means, said spacer means further including a pair of spaced-apart, opposed lateral surfaces, each lateral surface having an anterior end and a posterior end, said lateral surfaces being joined at their posterior ends by said rapidly tapering presenting portion, said lateral surfaces tapering apart from one another from their posterior ends to their anterior ends and being joined at their anterior ends by a face comprising a trailing edge portion, said lateral surfaces having a straight edge section when said spacer means is viewed from a plan view thereof, said straight edge sections being parallel to each other, said

opposed lateral surfaces each having two curvilinear sections, when said spacer means is viewed from an elevational view of said trailing edge portion, each curvilinear section tapering from a said straight edge section to an apex of each said opposed lateral surface.

16. The spacer means of Claim 15 wherein said apex of each opposed lateral surface includes a flat portion.

17. The spacer means of Claim 16 wherein said lateral surfaces taper apart from one another at an angle of about 5-8°.

18. The spacer means of Claim 17 wherein said spacer means is solid hydroxyapetite.

AMENDED CLAIMS
[received by the International Bureau on 20 June 1995 (20.06.95); original claim 6 cancelled; original claims 1,4,5,7, 10-12 and 14-18 amended; remaining claims unchanged (4 pages)]

1. An intervertebral spacer means for promoting anterior intervertebral fusion and sagittal alignment in a patient, said spacer means comprising a body comprising a material capable of bonding to natural bone and having a rapidly tapering presenting portion comprising a posterior end of said spacer means, said spacer means characterized by a pair of spaced-apart, opposed lateral surfaces, each lateral surface having an anterior end and a posterior end, said lateral surfaces being joined at their posterior ends by said rapidly tapering presenting portion, said lateral surfaces tapering apart from one another from their posterior ends to their anterior ends, when said spacer means is viewed from a lateral elevational view, and being joined at their anterior ends by a face comprising a trailing edge portion.

2. The spacer means of Claim 1, wherein at least one of said opposed lateral surfaces includes a convex portion, as viewed perpendicularly to the face comprising the trailing edge portion.

3. The spacer means of Claim 1, wherein said rapidly tapering presenting portion tapers to a convex tip, when viewed from both elevational and plan views of said spacer means.

4. The spacer means of Claim 3, wherein at least one of said opposed lateral surfaces of said spacer means is curvilinear in shape, when viewed perpendicularly from said trailing edge portion.

5. The spacer means of Claim 4, wherein said spacer means further includes a pair of parallel side portions when viewed from a plan view thereof.

7. The spacer means of Claim 1, wherein the spacer

means further comprises, at least in part, natural bone, a biocompatible orthopedic polymer material, a ceramic, a ceramic-coated metal, a composite, or a metal.

8. The spacer means of Claim 7, wherein the ceramic is hydroxyapatite.

9. The spacer means of Claim 7, wherein the metal is selected from the group consisting of titanium, titanium alloys, gold, vanadium/aluminum alloys, and stainless steel.

10. The spacer means of Claim 1, wherein the spacer means is microporous.

11. The spacer means of Claim 3, wherein the spacer means is universal in size for promoting anterior cervical fusion in adult human patients, being about 11-16 mm in length between the trailing edge portion and the convex tip of the presenting portion, the presenting portion being about 3-5 mm in length and being about 4-6 mm in width when said spacer means is viewed perpendicularly from an elevational view, the presenting portion further being about 6-8 mm in width when said spacer means is viewed perpendicularly from a plan view, the trailing edge portion being about 6-8 mm at its widest point when said spacer means is viewed perpendicularly from an elevational view and about 11-16 mm at its widest point when said spacer means is viewed perpendicularly from a plan view thereof.

12. The spacer means of Claim 11, wherein the spacer means being about 12 mm in length between the trailing edge portion and the convex tip of the presenting portion, the presenting portion being about 4 mm in length and being about 4-6 mm in height when said spacer means is viewed perpendicularly from an elevational view, the presenting portion further being about 7 mm in width at its widest

point when said spacer means is viewed perpendicularly from a plan view, the trailing edge portion being about 7 mm in height at its widest point when said spacer means is viewed perpendicularly from an elevational view and about 15 mm in width at its widest point when said spacer means is viewed perpendicularly from the anterior end thereof.

13. The spacer means of Claim 12 wherein said face of said trailing edge includes ellipsoidal sections, and both opposed lateral surfaces have a convex contour corresponding to said ellipsoidal sections of said trailing edge.

14. A system for promoting sagittal alignment of a patient's spine, comprising an intervertebral spacer means for promoting anterior intervertebral fusion in said patient, said spacer means comprising a solid body comprising a material capable of bonding to natural bone and having a rapidly tapering presenting portion comprising a posterior end of said spacer means, said spacer means characterized by a pair of spaced-apart, opposed lateral surfaces, each lateral surface having an anterior end and a posterior end, said lateral surfaces being joined at their posterior ends by said rapidly tapering presenting portion, said lateral surfaces tapering apart from one another from their posterior ends to their anterior ends, when said spacer means is viewed from a lateral elevational view, and being joined at their anterior ends by a face comprising a trailing edge portion, said system for providing anterior and posterior sagittal alignment in a region of said spine in which said spacer means is implanted.

15. An intervertebral spacer means for promoting anterior intervertebral fusion and sagittal alignment in a

patient, said spacer means comprising a material capable of bonding to natural bone and having a rapidly tapering presenting portion, characterized by said presenting portion having curvilinear segments in any plane of view of said presenting portion, said presenting portion tapering to a convex tip comprising a posterior end of said spacer means, said spacer means further including a pair of spaced-apart, opposed lateral surfaces, each lateral surface having an anterior end and a posterior end, said lateral surfaces being joined at their posterior ends by said rapidly tapering presenting portion, said lateral surfaces tapering apart from one another from their posterior ends to their anterior ends, when said spacer means is viewed from a lateral elevational view, and being joined at their anterior ends by a face comprising a trailing edge portion, said lateral surfaces having a straight edge section when said spacer means is viewed from a plan view thereof, said straight edge sections being parallel to each other, said opposed lateral surfaces each having two curvilinear sections, when said spacer means is viewed from an elevational view of said trailing edge portion.

16. The spacer means of Claim 15 wherein each opposed lateral surface includes a flat portion joined to said straight edge section by said curvilinear sections.

17. The spacer means of Claim 16 wherein said lateral surfaces taper apart from one another, from their posterior ends to their anterior ends, at an angle of about 5-8° when said spacer means is viewed from a lateral elevational view.

18. The spacer means of Claim 17 wherein said spacer means is solid hydroxyapatite.

STATEMENT UNDER ARTICLE 19

The claims of the subject case have been amended pursuant to Article 19(1) in order to more clearly define the invention and distinguish it from the prior art. All claims have now been amended to make clear that the intervertebral spacer of the present invention comprises a material capable of bonding to natural bone, distinguishing the present spacer, which promotes anterior intervertebral fusion, from a prosthesis, which does not promote such fusion.

The claims have further been amended to make more clear the requirement that the lateral surfaces of the spacer (upper and lower surfaces) taper apart from one another from their posterior ends to their anterior ends when the spacer is viewed from a lateral elevational view. This more clearly distinguishes the present invention form intervertebral spacers of the prior art which include only parallel upper and lower surfaces. The tapered upper and lower lateral surfaces of the present invention allow the spacer to more readily approximate the intervertebral space, thereby providing increased contact between the spacer and boney regions of adjoining vertebrae, increasing the surface area available for fusion, and increasing consequent strength of the fused vertebrae.

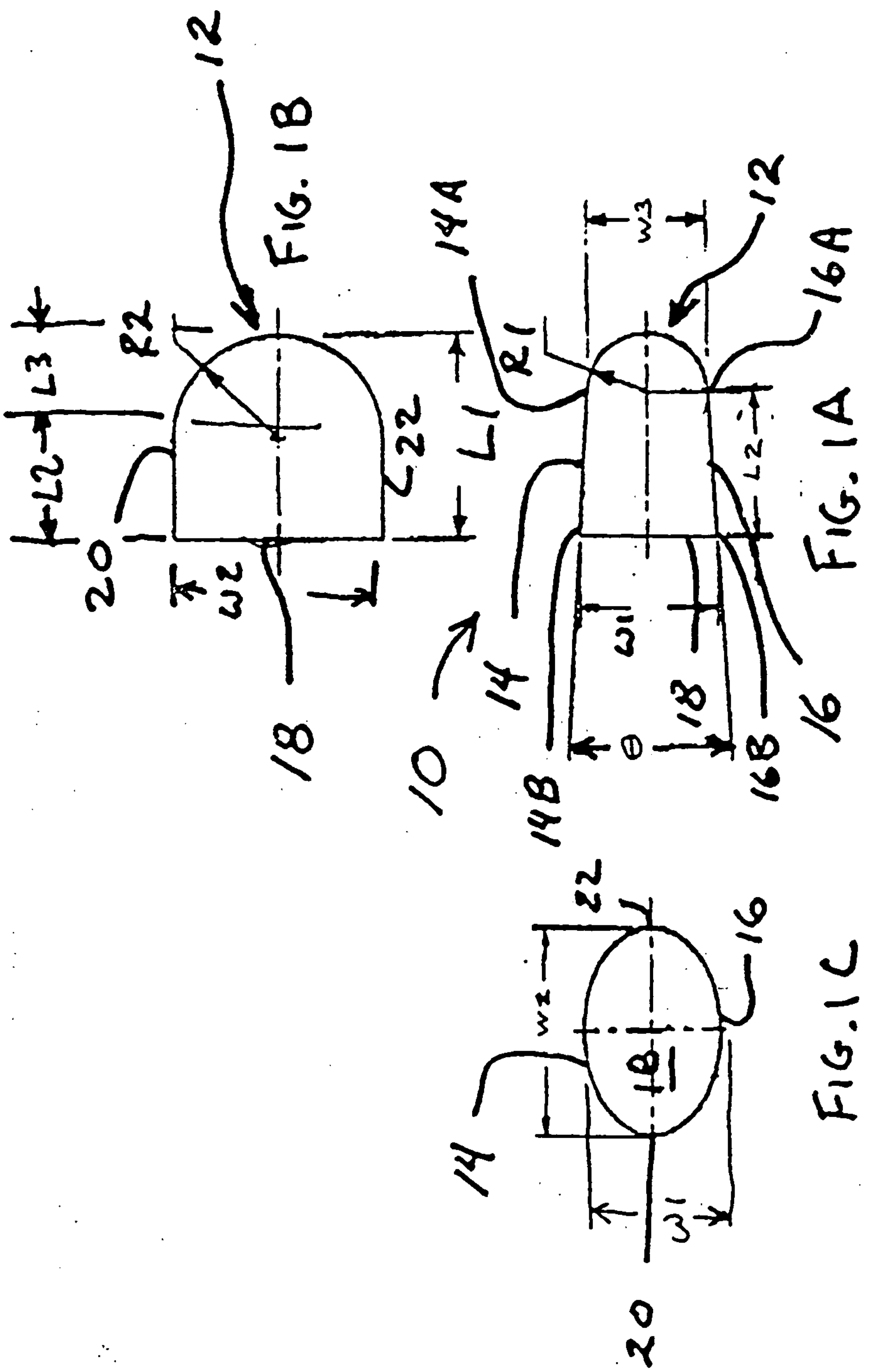
FIG. 1B
FIG. 1A
FIG. 1C

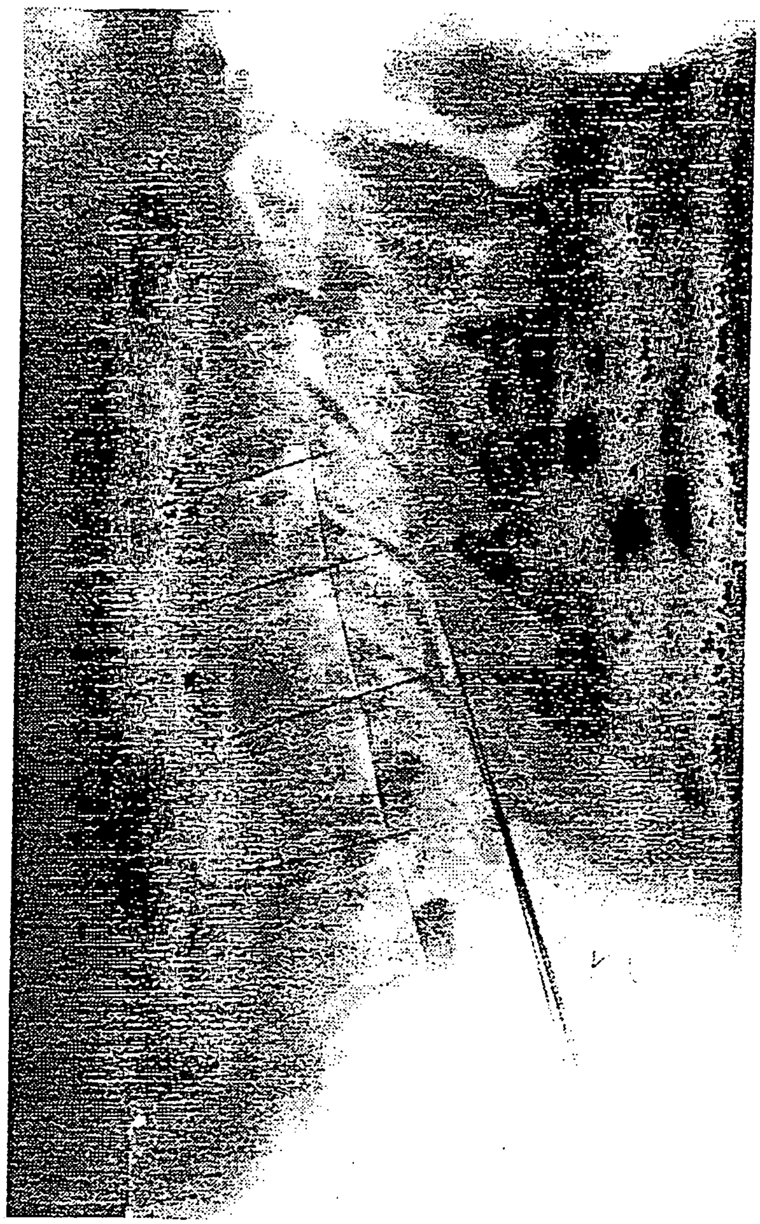

FIGURE 2

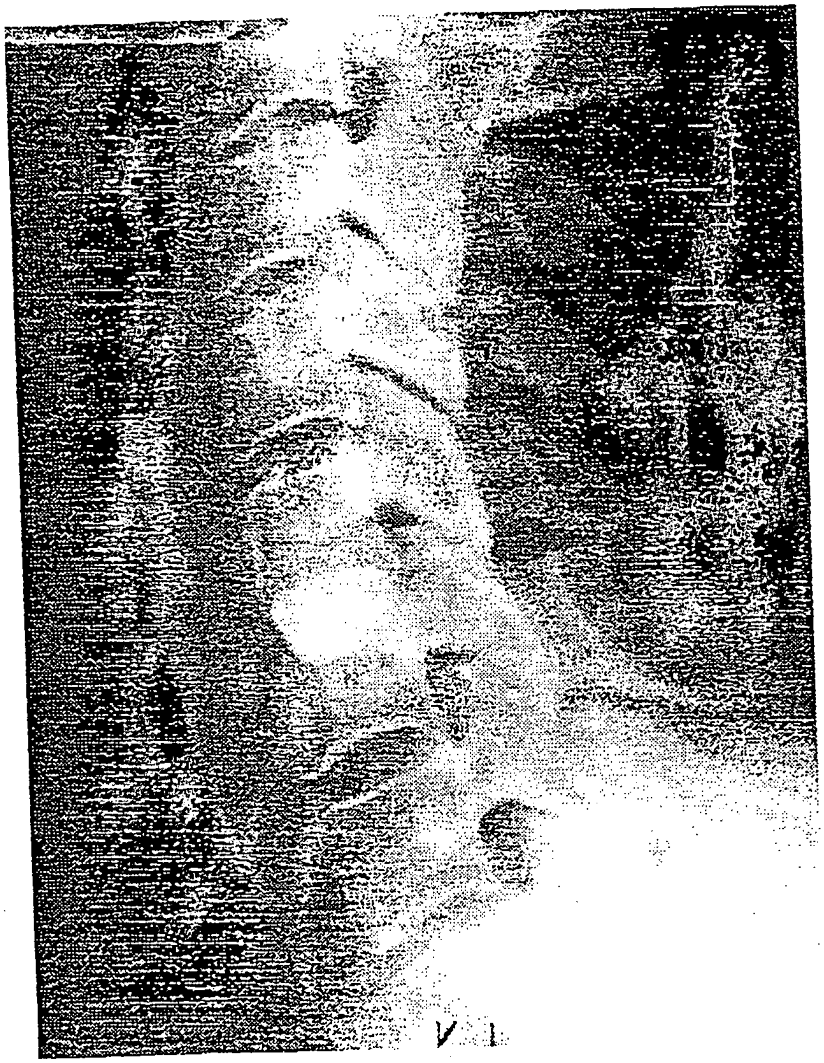

Figure 3

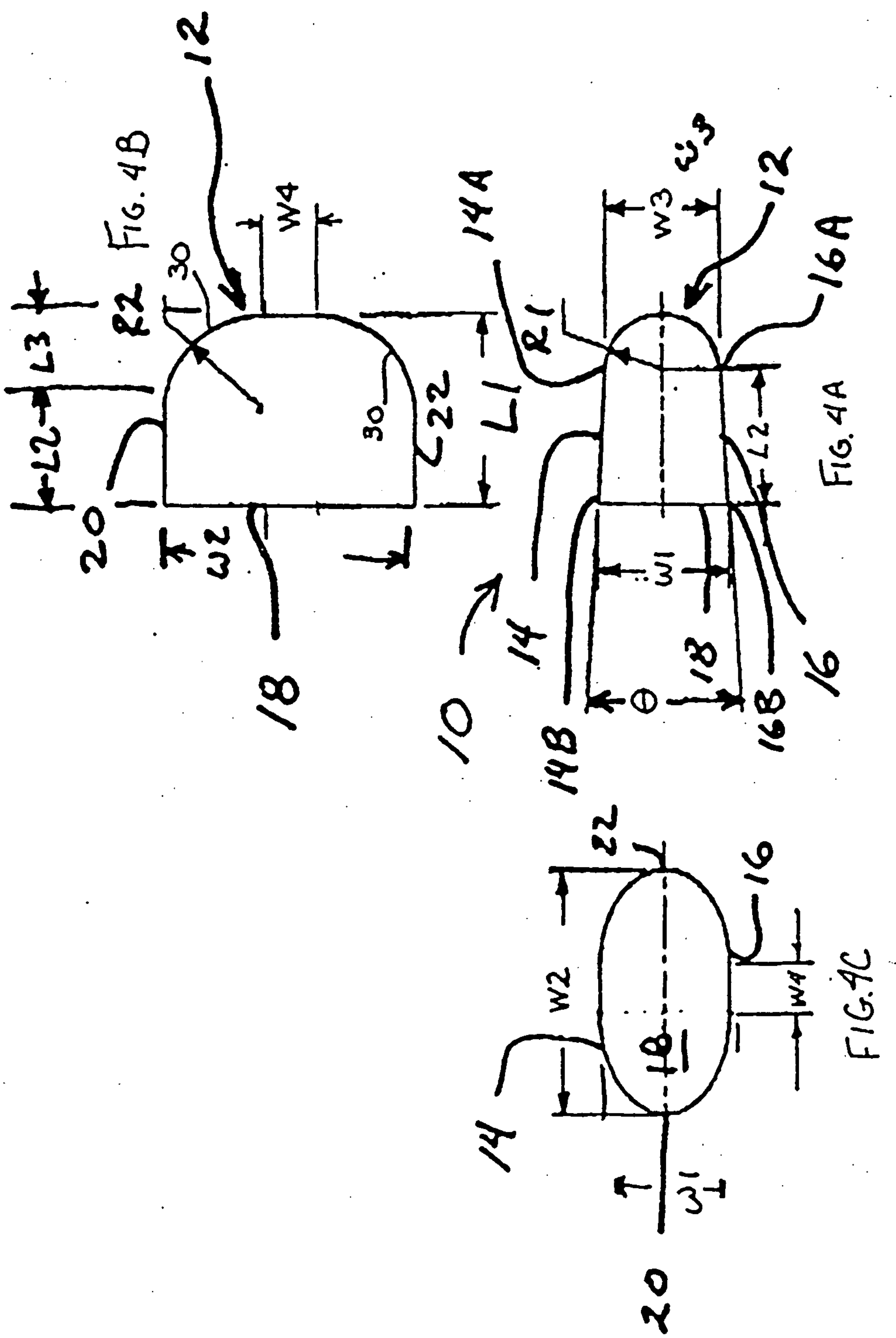

FIG. 4B

FIG. 4A

FIG. 4C